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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC-2015-0063, NIOSH-287]

RIN 0920-AA61

World Trade Center Health Program; Addition of New-Onset Chronic Obstructive Pulmonary Disease and WTC-Related Acute Traumatic Injury to the List of WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: The World Trade Center (WTC) Health Program conducted a review of published, peer-reviewed epidemiologic studies regarding potential evidence of chronic obstructive pulmonary disease (COPD) and acute traumatic injury among individuals who were responders to or survivors of the September 11, 2001, terrorist attacks. The Administrator of the WTC Health Program (Administrator) found that these studies provide substantial evidence to support a causal association between each of these health conditions and 9/11 exposures. As a result, the Administrator is publishing a final rule to add both new-onset COPD and WTC-related acute traumatic injury to the

List of WTC-Related Health Conditions eligible for treatment coverage in the WTC Health Program.

DATES: This rule is effective on [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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I. Executive Summary

A. Purpose of Regulatory Action

This rulemaking is being conducted in order to add new-onset COPD and WTC-related acute traumatic injury¹ to the List of WTC-Related Health Conditions (List). Following the receipt of letters from the directors of the WTC Health Program Clinical Centers of Excellence (CCEs) and Data Centers to the WTC Health Program supporting coverage of all cases of COPD (including new-onset COPD) and significant traumatic injuries within the Program,² the Administrator decided to conduct literature reviews

¹ The term "WTC-related" was not included in the proposed definition of acute traumatic injury in the notice of proposed rulemaking, 80 FR 54746 (Sept. 11, 2015), but has been added in the final rule to clarify specific usage in the WTC Health Program and better parallel "WTC-related musculoskeletal disorder" on the List. The Administrator finds that revising the term results in no substantive change from the proposed rule. See discussion *infra* Section VIII.

² Michael Crane, Roberto Lucchini, Jacqueline Moline, *et al.*, Letter from CCE and Data Center Directors to Dori Reissman and John Halpin, WTC Health Program Regarding "Musculoskeletal Conditions," May 11, 2014; and Michael Crane, Roberto Lucchini, Jacqueline Moline, *et al.*, Letter from CCE and Data Center Directors to Dori Reissman and John Halpin, WTC Health Program Regarding "Rationale for the Continued Certification of COPD as a World Trade Center Related and Covered Condition," Apr. 22, 2014. These letters are included in the docket for this rulemaking.

regarding COPD and acute traumatic injuries among 9/11 responders and survivors. Based on the findings of those reviews, he determined that the evidence for causal associations between 9/11 exposures and new-onset COPD and acute traumatic injury, respectively, provides sufficient bases for the addition of both health conditions to the List. The Administrator published a proposed rule to add new-onset COPD and acute traumatic injury to the List on September 11, 2015,³ and finalizes the rule in this action.

B. Summary of Major Provisions

This final rule adds new-onset COPD and WTC-related acute traumatic injury to the List of WTC-Related Health Conditions in 42 CFR 88.1. As of the effective date of this rule, these conditions will be eligible for treatment by the WTC Health Program.

C. Costs and Benefits

The addition of new-onset COPD and WTC-related acute traumatic injury to the List of WTC-Related Health Conditions through this rulemaking is estimated to cost the WTC Health Program from \$4,602,162 to \$5,666,713 annually, between 2016 and 2019. All of the costs to the WTC Health

³ 80 FR 54746.

Program are transfers. Benefits to current and future WTC Health Program members may include improved access to care and better treatment outcomes than in the absence of Program coverage.

II. Public Participation

On September 11, 2015, the Administrator published a notice of proposed rulemaking (NPRM) to propose the addition of new-onset COPD and acute traumatic injury to the List in 42 CFR 88.1.⁴ The Administrator asked peer reviewers to evaluate the scientific literature review and Administrator's determination and invited interested members of the public or organizations to participate in the rulemaking by submitting written views, opinions, recommendations, and/or data. This final rule describes feedback received from both peer reviewers and public commenters.

A total of six peer reviewers were charged with reviewing the Administrator's evaluation of the evidence for adding the two conditions to the List. Three pulmonary disease experts reviewed the evidence for the addition of new-onset COPD and three injury experts reviewed the

⁴ Id.

evidence for the addition of acute traumatic injury. Specifically, the peer reviewers were asked to answer the following questions:

1. Are you aware of any other studies which should be considered? If so, please identify them.
2. Have the requirements of the Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions⁵ appropriately been fulfilled? If not, please explain which elements are missing or deficient.
3. Is the interpretation of the available data appropriate, and does it support the conclusion? If not, please explain why.

Public comments were invited on any topic related to the proposed rule, and specifically⁵ on the following questions:

1. Is September 11, 2003 an appropriate deadline by which an individual must have received initial medical treatment for an acute traumatic injury?
2. Is there evidence of acute traumatic injuries that occurred as a result of the September 11, 2001, terrorist attacks that would not be covered by the

⁵ John Howard, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, revised Oct. 21, 2014, http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.

proposed definition? What are the types of long-term consequences or medically associated health conditions that result from the treatment or progression of acute traumatic injuries like those sustained on or after September 11, 2001?

3. Are data available on the chronic care needs of individuals who suffered acute traumatic injuries during the September 11, 2001, terrorist attacks, and its aftermath that the Administrator can use to estimate the number of current and future WTC Health Program members who may seek certification of WTC-related acute traumatic injury as well as treatment costs?
4. Are data available on the prevalence and cost estimates for new-onset COPD?

The Administrator received 16 submissions to the rulemaking docket from the public, including the following individuals and organizations: 10 unaffiliated commenters; one individual who is a responder or survivor; two self-identified responders; sister non-profit organizations dedicated to preventing and curing alpha-1 antitrypsin deficiency and COPD; a labor union; and the WTC Health Program Survivors and Responders Steering Committees.

The peer reviews and public comments are found in the docket for this rulemaking. Summaries of all peer reviews and public comments, as well as the Administrator's responses, are found below.

III. Background

A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), Public Law 111-347, as amended by Public Law 114-113, added Title XXXIII to the Public Health Service Act (PHS Act),⁶ establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked,

⁶ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Pub. L. 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this document mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee. Section 3312(a)(6) of the PHS Act requires the Administrator to conduct rulemaking to propose the addition of a health condition to the List codified in 42 CFR 88.1.

B. Evidence Supporting the Addition of New-Onset COPD and WTC-Related Acute Traumatic Injury to the List of WTC-Related Health Conditions

Consideration of an addition to the List may be initiated at the Administrator's discretion⁷ or following receipt of a petition by an interested party.⁸ Under 42 CFR 88.17, the Administrator has established a process by which health conditions may be considered for addition to the List of WTC-Related Health Conditions in § 88.1. Pursuant to section 3312(a)(6)(D) of the PHS Act, whenever the Administrator determines that a condition should be proposed for addition to the List, he is required to

⁷ PHS Act, sec. 3312(a)(6)(A); 42 CFR 88.17(b).

⁸ PHS Act, sec. 3312(a)(6)(B); 42 CFR 88.17(a).

publish an NPRM and allow interested parties to comment on the proposed rule.

The Administrator also follows the WTC Health Program's policy and procedures for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions, published online in the Policies and Procedures section of the WTC Health Program website.⁹ The Administrator amended the policy since it was used to conduct the analysis of COPD and acute traumatic injury studies for the NPRM;¹⁰ changes to the policy are not substantive and are intended to clarify terminology and specific procedures. The policy's descriptions of what studies will be evaluated in the literature evidence review and analyzed in the scientific and medical assessment have been revised to clarify the types of studies considered peer-reviewed, published, epidemiologic studies.¹¹ The Administrator has also revised an existing footnote regarding distinct criteria for assessing certain

⁹ John Howard, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, revised May 11, 2016, http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf.

¹⁰ An October 2014 version of the policy was used to conduct the review in the September 2015 NPRM. See John Howard, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, revised Oct. 21, 2014, http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.

¹¹ The clarification of the description of the studies was made in response to peer review comments on the WTC-related acute traumatic injury analysis. See discussion of these comments infra Section VI. A.

conditions with immediate and observable cause and effect.¹² These criteria were already included in the assessment conducted for the analysis of acute traumatic injury studies published in the NPRM.¹³ In accordance with the policy, the Administrator directed the WTC Health Program Associate Director for Science (ADS) to conduct a review of the scientific literature to determine if the available scientific information on COPD and acute traumatic injury, respectively, had the potential to provide a basis for a decision on whether to add the conditions to the List. The literature review included published, peer-reviewed epidemiologic studies, including direct observational studies,¹⁴ about each health condition among 9/11-exposed populations. The studies were reviewed for their relevance, quantity, and quality to determine whether they had the potential to provide a sufficient basis for the Administrator's decision to propose adding each health condition to the List.

¹² The footnote to the policy explains that injury studies are assessed for relevance, quantity, quality, known causation, and onsite occurrence and that information in the studies about injuries recorded in contemporaneous medical records and studies, combined with known hazards and known connections between those hazards and injury, may be useful to the Administrator's evaluation of any support for a causal association between those exposures and the injury. See footnote 12, John Howard, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, revised May 11, 2016, http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf.

¹³ 80 FR 54746, 54754.

¹⁴ See discussion of these terms infra Section IV.A.

After finding that the available evidence had the potential to provide bases for the decisions, the ADS further assessed the scientific and medical evidence to determine whether causal associations between 9/11 exposures and new-onset COPD and acute traumatic injury, respectively, were supported. A health condition may be added to the List if published, peer-reviewed epidemiologic studies provide substantial support¹⁵ for a causal association between 9/11 exposures and the health condition in 9/11-exposed populations.

In this case, the Administrator finds there is substantial evidence in published, peer-reviewed epidemiologic studies that 9/11 exposures produced chronic airway inflammation manifested by persistent lower respiratory symptomatology and decline in pulmonary function, which progressed to new-onset COPD in a proportion of exposed subjects in the period since exposure, independently from any cigarette smoking among the cohort. This evidence provides substantial support for a causal association between 9/11 exposures and new-onset COPD.

¹⁵ The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

The Administrator also finds that evidence in the published, peer-reviewed epidemiologic studies evaluated by the ADS provides substantial support for a causal association between 9/11 exposures and acute traumatic injuries among responders and survivors to the September 11, 2001, terrorist attacks.

The reviews of evidence and Administrator's determinations concerning the addition of new-onset COPD¹⁶ and WTC-related acute traumatic injury¹⁷ are found, in full, in the NPRM.

IV. Effects of Rulemaking on Federal Agencies

Title II of the Zadroga Act reactivated the September 11th Victim Compensation Fund (VCF). Administered by the U.S. Department of Justice (DOJ), the VCF provides compensation to any individual or representative of a deceased individual who was physically injured or killed as a result of the September 11, 2001, terrorist attacks or during the debris removal. Eligibility criteria for compensation by the VCF include a list of presumptively covered health conditions, which are physical injuries determined to be WTC-related health conditions by the WTC

¹⁶ See 80 FR 54746 at 54748.

¹⁷ Id. at 54752-54754.

Health Program. Pursuant to DOJ regulations, the VCF Special Master is required to update the list of presumptively covered conditions when the List of WTC-Related Health Conditions in 42 CFR 88.1 is updated.¹⁸

V. Summary of Peer Reviews and Public Comments -- New-Onset COPD

As discussed above in the Public Participation section, the Administrator solicited reviews of the NPRM by three experts in the field of pulmonary disease who provided peer review of the evidence supporting the addition of new-onset COPD. In addition to the peer reviews, the Administrator received submissions from public commenters. The COPD-related peer reviews and public comments are summarized below, and each is followed by a response from the Administrator.

A. Peer Review

First, peer reviewers were asked whether they were aware of any other studies which should have been considered in the NPRM, with regard to new-onset COPD. Second, the peer reviewers were asked whether the

¹⁸ 28 CFR 104.21(b).

requirements of the Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, described above, had been fulfilled. Third, the peer reviewers were asked whether the Administrator's interpretation of the evidence for new-onset COPD was appropriate and whether it supported the decision to propose adding new-onset COPD to the List.

Identification of other studies to support the Administrator's determination

One new-onset COPD peer reviewer indicated that no additional articles concerning 9/11 exposures and new-onset COPD were identified. Two reviewers suggested additional studies that the Administrator should have considered.

One reviewer suggested three additional studies for the Administrator's consideration, two of which referenced 9/11 exposures among WTC responders with lower respiratory symptoms. The first study, Mauer et al.,¹⁹ did not include spirometry, and the second study, Niles et al.,²⁰ did not specifically address the occurrence of COPD among the 9/11-exposed population but examined the extent to which early post-disaster symptoms and diagnoses accurately anticipate

¹⁹ Matthew Mauer, Karen Cummings, Rebecca Hoen, Long-Term Respiratory Symptoms in World Trade Center Responders, *Occup Med (Lond)* 2010;60(2):145-51.

²⁰ Justin Niles, Mayris Webber, Hillel Cohen, et al., The Respiratory Pyramid: From Symptoms to Disease in World Trade Center Exposed Firefighters, *Am J Ind Med* 2013;56(8):870-80.

future healthcare needs. The third study, Lange et al.,²¹ was not an epidemiologic study of 9/11-exposed populations, and thus was not further considered. As stated in the NPRM preamble, only epidemiologic studies that reported compatible new-onset, "post-9/11 lower respiratory symptomatology and objective measurements of airways obstruction, such as pre- and post-9/11 spirometry with bronchodilator administrator or IOS [impulse oscillometry] were found to exhibit potential support"²² for a recommendation to add the health condition to the List and selected for further quality review. Since the Mauer and Niles studies did not meet this standard, they were not further reviewed.

The other reviewer suggested a review of the literature on non-smoking inhalational exposures, which are responsible for 15 percent of COPD cases, and noted that COPD can present years after relevant exposures. The Administrator agrees that COPD attributed to occupational and environmental exposures may present several years after cessation of exposures; however, the matter of maximum time intervals for the diagnosis of new-onset COPD is outside

²¹ Peter Lange, Bartolome Celli, Alvar Agustí, et al., Lung-Function Trajectories Leading to Chronic Obstructive Pulmonary Disease, N Engl J Med 2015;373:111-122.

²² 80 FR 54746 at 54749.

the scope of this rulemaking and will be addressed through Program policy and procedures.

One general comment recommended that the full search string be included in future assessments so that reviewers can replicate the literature search. The Administrator agrees; future assessments will include full search strings so that reviewers may replicate the ADS's literature review.²³

Administrator's compliance with established policy and procedures to add non-cancer health conditions to the List of WTC-Related Health Conditions

All three of the new-onset COPD peer reviewers agreed that the requirements of the policy had been fulfilled.

Administrator's interpretation of evidence for the addition of new-onset COPD

All three new-onset COPD reviewers found that the interpretation of the available literature was appropriate and supported the Administrator's conclusion. One reviewer identified challenges with establishing an operational definition of COPD and how the definition would be applied

²³ In the case of COPD, the full search string consisted of the following: ("chronic obstructive pulmonary disease" OR "chronic bronchitis" OR "pulmonary emphysema" OR "pulmonary function decline" OR "respiratory insufficiency" OR "airways obstruction" OR "airflow limitation") AND ("September 11 Terrorist Attacks" OR "World Trade Center" OR WTC OR "September 11" OR 9/11).

to WTC Health Program members. The reviewer asked whether an individual with potentially relevant symptoms (such as lower respiratory symptoms or symptoms of chronic bronchitis) and normal spirometry has COPD. The commenter noted that "obstructive chronic bronchitis," included in the description of COPD in the NPRM preamble, does not appear in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) recommendations, and its inclusion in the NPRM preamble implies that the WTC Health Program member would not be considered to have COPD if diagnosed with chronic bronchitis in the absence of demonstrated airflow obstruction. The reviewer also asked whether impulse oscillometry alone can support a COPD diagnosis, and pointed out that GOLD does not include impulse oscillometry as a diagnostic test for COPD. Finally, the reviewer asked whether the WTC Health Program will require identification of emphysema, included under the COPD category, by computerized tomography (CT) scan imaging even in the absence of demonstrated spirometric airflow obstruction.

The reviewer accurately notes the difficulties in choosing a single definition of COPD for the purpose of this rulemaking. As discussed in the NPRM, COPD is an umbrella term and encompasses a variety of pulmonary

conditions; various definitions exist, making the interpretation of evidence for adding new-onset COPD to the List a challenge. The GOLD definition of COPD, which requires spirometric evidence of airflow limitation, was used to provide an objective parameter to evaluate the occurrence of COPD among the 9/11-exposed populations identified in the surveillance literature reviewed by the ADS. Chronic obstructive bronchitis is a subtype of chronic bronchitis associated with airflow limitation, as recognized by the National Heart, Lung, and Blood Institute.²⁴ Relying on the Merck Manual, the NPRM preamble utilized a definition of "obstructive chronic bronchitis" that emphasizes the need for spirometric evidence of airflow obstruction.

Diagnosis of COPD requires confirmation, using spirometry, of airflow limitation that is not fully reversible, as well as a history of potentially causative exposure among symptomatic individuals. In some circumstances, in addition to spirometry, impulse oscillometry may be presented to support the COPD diagnosis by detecting subtle changes in a patient's airways function earlier than with conventional spirometry.²⁵

²⁴ See NIH, National Heart, Lung, and Blood Institute, Executive Summary, <http://www.nhlbi.nih.gov/research/reports/2011-bronchitis>.

²⁵ Christopher Cooper, Assessment of Pulmonary Function in COPD, *Semin Respir Crit Care Med* 2005;26(2):246-52.

The WTC Health Program will provide specific instruction to physicians regarding diagnostic standards for new-onset COPD. Certification of cases of new-onset COPD in individual WTC Health Program members will be decided by the Program on a case-by-case basis, in accordance with section 3312(b)(2)(B) of the PHS Act and 42 CFR 88.13.

B. Public Comment

Support for new-onset COPD

Many commenters expressed support for the addition of new-onset COPD to the List. One commenter found that the Administrator presented quality evidence that establishes a causal association between 9/11 exposures and new-onset COPD. Although some submissions only addressed the addition of acute traumatic injury, no commenters opposed the addition of new-onset COPD.

Additional studies to support the addition of new-onset COPD to the List

One commenter suggested the consideration of a 2010 study by Banauch et al.²⁶ to support the addition of COPD to

²⁶ Gisela Banauch, Mark Brantley, Gabriel Izbicki, et al., Accelerated Spirometric Decline in New York City Firefighters with α 1-Antitrypsin Deficiency, CHEST 2010;138(5):1116-1124.

the List. Another commenter offered a list of additional articles that should have been reviewed.

The Banauch study was reviewed and found to be relevant; however, it was not selected to undergo further evidence review due to its small number of study participants (n=90). The papers cited by the second commenter were reviewed during the literature review process; however, only epidemiologic studies that reported compatible post-9/11 lower respiratory symptomatology and objective measurements of airways obstruction, such as pre- and post-9/11 spirometry with bronchodilator administration or impulse oscillometry were found to exhibit potential for a recommendation and selected for review. Two of the references offered by the commenter, Aldrich et al. and Weakley et al., were included in the ADS's review published in the NPRM.

VI. Summary of Peer Reviews and Public Comments -- WTC-Related Acute Traumatic Injury

As discussed above in the Public Participation section, the Administrator solicited reviews of the NPRM by three injury experts who provided peer review of the evidence supporting the addition of acute traumatic injury.

In addition to the peer reviews, the Administrator received submissions from public commenters. All of the acute traumatic injury-related peer reviews and public comments are summarized below, and each is followed by a response from the Administrator.

A. Peer Review

First, with regard to acute traumatic injury, peer reviewers were asked whether they were aware of any other studies which should have been considered in the NPRM. Second, the peer reviewers were asked whether the requirements of the Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, described above, had been fulfilled. Third, the peer reviewers were asked whether the Administrator's interpretation of the evidence for the addition of acute traumatic injury was appropriate and whether it supported the decision to propose adding acute traumatic injury to the List.

Identification of other studies to support the Administrator's determination

All three acute traumatic injury peer reviewers indicated that they were unaware of any additional studies

concerning acute traumatic injury that should have been considered by the Administrator. One reviewer suggested that a complete list of citations that were excluded from the ADS's review as not relevant should have been provided to reviewers. The Administrator agrees to make the full list of citations identified in the literature review as well as excluded scientific papers available to reviewers in future rule-related peer reviews.²⁷

Administrator's compliance with established policy and procedures to add non-cancer health conditions to the List of WTC-Related Health Conditions

Two of the acute traumatic injury peer reviewers found that the requirements of the policy had been fulfilled. One reviewer asked about the intent of describing the studies

²⁷ The table below provides the search strings used to conduct the literature search; the full list of citations identified by the literature search conducted by the ADS is not provided here. The NPRM incorrectly identified search terms used in the literature review (80 FR 54746 at 54752); the terms identified in the NPRM were instead terms used to develop cost estimates for the Executive Order 12866 and Executive Order 13563 analysis in Section VIII.A.

Database	Search terms	Results
PubMed	("September 11 Terrorist Attacks"[Mesh] OR "World Trade Center"[TIAB] OR WTC [TIAB] OR "September 11"[TIAB]) AND ("Wounds and Injuries"[Mesh] OR "Occupational Injuries"[Mesh] OR "Cumulative Trauma Disorders"[Mesh] OR Injuries[TIAB]) From 2001/09/01 to 2014/12/31	114
CINAHL	(MH "Wounds and Injuries+") AND ("World Trade Center" OR "September 11")	36
Web of Science	("World Trade Center" OR "September 11") AND (Injury or injuries)	147
EMBASE	World Trade Center.mp. OR September 11.mp. AND exp injury/ (english language and embase and yr="2001 -Current")	191
Health & Safety Science Abstracts	("World Trade Center" OR "September 11") AND (injuries OR injury)	31
NIOSH TIC-2	World Trade Center (Title) AND Injury or Injuries (All Fields)	22

discussed in the assessment as “direct observational studies rather than epidemiologic studies,” further asking whether it meant that causation is in question or that rates could not be computed.

The October 2014 version of the WTC Health Program’s policy and procedures on adding non-cancers to the List used to evaluate acute traumatic injury studies for the NPRM distinguished between those types of epidemiologic studies that can be used to identify causal associations between exposures and health outcomes such as diseases, and those studies that can be used to identify causal associations between exposures and health outcomes such as cases of injury.²⁸ The terminology “direct observational studies” was an attempt to use plain language to describe the types of studies that could provide relevant evidence of a causal association between 9/11 exposures and a health outcome, such as an injury. However, rather than making the intent clear, it appears that the term may be confusing. By describing the studies used to identify certain health outcomes as “direct observational studies,” the WTC Health Program intended to describe studies which are more often referred to as “descriptive epidemiologic studies” within

²⁸ See John Howard, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, revised Oct. 21, 2014, http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf.

the scientific community. As discussed above, recent amendments to the policy clarify the terminology to mitigate confusion regarding the types of information sources the WTC Health Program uses to support the addition of certain health conditions to the List.²⁹

In accordance with both the previous and current policy and procedures on adding non-cancers to the List used to develop this rulemaking, the ADS searched published, peer-reviewed epidemiologic studies of acute traumatic injuries in the 9/11-exposed population, including studies referred to in the October 2014 policy as "direct observational studies." The epidemiologic studies reviewed for this rulemaking to support the addition of WTC-related acute traumatic injury to the List document that outcomes occurred because of the 9/11 exposures and, thus, can be used to establish a causal association between the 9/11-related event, such as being struck by falling debris, and the injury, such as a broken arm. The studies reviewed allow the Administrator to conclude that certain types of acute traumatic injury suffered by WTC responders and survivors were sustained during or in the aftermath of the September 11, 2001, terrorist attacks and find that the

²⁹ John Howard, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, revised May 11, 2016, http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf

evidence provides substantial support for a causal association between acute traumatic injury and 9/11 exposures.

The reviewer also found it difficult to assess adherence to the policy because of a perceived lack of clarity with regard to the scope of the Administrator's inquiry and suggested that injuries should be identified as "acute," "subacute," and "chronic." The reviewer further questioned the distinction between a broad understanding of injuries which are musculoskeletal in nature and the Administrator's definition of "acute traumatic injury" and suggested the removal of a statement found in the NPRM characterizing musculoskeletal disorders as distinct from acute traumatic injuries, pointing out that many of the types of acute traumatic injury identified by the Administrator are musculoskeletal in nature. The reviewer suggested that the Administrator should have better clarified the distinction between acute and chronic traumatic injury (injuries caused by multiple exposures over time) and recommends that such a discussion be added to the analysis in the NPRM. Without this more robust discussion, the reviewer questioned how the definition of acute traumatic injury will be applied, particularly with regard to the timing of initial medical care post-injury,

diagnosis of head trauma, treatment of chronic pain, medically associated health conditions, and pre-existing injuries.

The term "WTC-related musculoskeletal disorder" is defined in the PHS Act and statements in the NPRM regarding "musculoskeletal disorders" are based on, and are consistent with, the statutory definition which sets out a clear standard for identifying chronic or recurrent disorders of the musculoskeletal system, caused by heavy lifting or repetitive strain.³⁰ In contrast to the term "chronic traumatic injury," used by the reviewer, the Administrator defines a "WTC-related acute traumatic injury" as an injury that occurred suddenly during one incident involving exposure to an external event. The new definition of "WTC-related acute traumatic injury" may capture musculoskeletal injuries which do not meet the statutory definition of "WTC-related musculoskeletal disorder." The purpose of this action is to provide Program coverage for those injuries that do not meet the existing definition of WTC-related musculoskeletal disorder, such

³⁰ Pursuant to sec. 3312(a)(4) of the PHS Act, "WTC-related musculoskeletal disorder" means a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks. For a WTC responder who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003, eligible musculoskeletal disorders include: (i) Low back pain; (ii) Carpal tunnel syndrome [CTS]; (iii) Other musculoskeletal disorders. See also 42 CFR 88.1.

as, for example, those not caused by heavy lifting or repetitive strain.

The reviewer's detailed questions regarding how the definition of WTC-related acute traumatic injury will be operationalized will be answered in forthcoming guidance to CCE and NPN physicians. Each WTC Health Program member's health condition will be evaluated in accordance with the Program's published policies and procedures.

Administrator's interpretation of evidence for the addition of acute traumatic injuries

Two of the acute traumatic injury peer reviewers found the Administrator's interpretation of the available data to be appropriate.

One reviewer found the presentation of data to be confusing and the Administrator's final determination concerning the addition of acute traumatic injury to the List unclear with regard to its scope. The reviewer acknowledged that the ADS may have encountered difficulties obtaining evidence of injury severity and outcomes, which the reviewer felt were crucial to a true understanding of the chronicity or level of injury severity, and disagreed with the Administrator's conclusion regarding the types of acute traumatic injuries identified by the literature.

According to the reviewer, the documentation of extreme injuries in the surveillance literature should not lead to conclusions regarding the types of injuries and their outcomes. The reviewer suggested various edits to the Administrator's assessment of the data, published in the NPRM, to either omit the word "severe" in reference to burns, or define it in terms of total body surface area and burn depth, and to clarify that the severity of injury could not be ascertained from the studies reviewed. The reviewer disagreed with the Administrator's conclusion that an eye injury, such as corneal abrasion, could be caused by an exposure to energy. Ultimately, the reviewer disagreed with the Administrator's proposed definition of acute traumatic injury and instead suggested that the Administrator define trauma as a cause of injury. Such injuries would include all types of traumatic events regardless of the body area or organ system injured. Examples include, but are not limited to head injury, burns, ocular injury, fractures, and tendon and other soft-tissue injuries.

In his evaluation of the data quality, the Administrator acknowledged that some information was not captured by the studies, and although he agrees that a full understanding of the severity of injuries suffered on or

after September 11, 2001 may not be gleaned from the studies reviewed, he found that the data were sufficient to corroborate the findings of the CCEs and Data Centers and to develop a broad definition of "acute traumatic injury." The use of the word "severe" to describe burns was intended to reflect the request made by the CCE and Data Center directors, which referred to the types of injuries they were seeing as "significant" and "severe." As discussed in the NPRM preamble, the types of injuries described by the CCE and Data Center directors are those that are most likely to result in the need for the services provided by the WTC Health Program and thus are those that the Administrator intended to capture by adding this health condition to the List. However, the Administrator agrees that the word "severe" is not defined, either in the surveillance literature or by the Administrator in the NPRM preamble. The word "severe," as used to describe burns in the proposed definition of "acute traumatic injury," is stricken from the final regulatory text in response to this review.

The Administrator's intent is to add coverage of acute traumatic injury caused by 9/11 exposures. The reviewer's proposal incorporates all types of trauma, including chronic or recurrent disorders of the musculoskeletal

system, caused by heavy lifting or repetitive strain, which are already covered for responders by the Program under the PHS Act's definition of "WTC-related musculoskeletal disorder." The edits proposed by the reviewer would not substantively alter the evaluation of the available literature or the Administrator's determination that the available scientific evidence supports adding WTC-related acute traumatic injury to the List.

The Administrator based the regulatory definition of WTC-related acute traumatic injury on several established definitions, including the definition used by the NIOSH Traumatic Injury Program which was accepted by the National Academy of Sciences in 2008.³¹ The regulatory definition is intended to address the etiology of the injury -- that is, that it occurred as the result of a single incident. The incident, characterized by an "exposure to energy," could include the movement of dust particles across the surface of the cornea, and result in an eye injury, such as a corneal abrasion. Because subacute and chronic conditions describe further stages after the injury has occurred, adding these additional categorizations to the regulatory

³¹ Committee to Review the NIOSH Traumatic Injury Research Program, Institute of Medicine and National Research Council, Traumatic Injury Research at NIOSH, 2009, <http://www.nap.edu/catalog/12459/traumatic-injury-research-at-niosh>.

definition is unnecessary. The regulatory definition includes all acute injuries that meet the definition.

The reviewer also asserted that the September 11, 2003 treatment cut-off "seems excessively long for most types of acute trauma but too short for others," and is not supported by evidence. According to the reviewer, the data presented in the NPRM demonstrated that most acute traumatic injuries were treated within hours of being sustained, although traumatic brain injuries may not have been identified for years after the event.

The Administrator agrees that the evidence reviewed in the NPRM demonstrates that most acute traumatic injuries were treated soon after they were sustained. The end date for initial treatment is well beyond the response and recovery period for the three sites and generously allows for delays in seeking treatment. The Administrator acknowledges that most responders and survivors who sustained acute traumatic injuries would have received medical treatment long before September 11, 2003. The reviewer also accurately points out that numerous cases of traumatic brain injury (TBI) identified in the Rutland-Brown paper, included in the ADS's review published in the NPRM,³² were not diagnosed as TBI within 3 years of the

³² See 80 FR 54746 at 54753.

exposure. However, each of these persons was admitted to a hospital for injuries/illnesses related to the September 11, 2001, terrorist attacks and treated for head injury or major trauma, but was not diagnosed with TBI at the time they initially received medical care. The regulatory text does not require the member to have been diagnosed with a TBI on or before September 11, 2003, only that he or she received medical attention for an acute traumatic injury by that date. When operationalizing the addition of WTC-related acute traumatic injury, the Program will ensure that this is clearly explained to the CCEs and the NPN. The Administrator finds that the September 11, 2003 deadline is consistent with the evidence presented in the NPRM and is neither too long nor too short for its intended purpose of offering a reasonable amount of time in which to expect that an injury sustained on or after September 11, 2001 was treated. As discussed in the NPRM preamble, the decision was made to set the end-date because this was the date used to identify traumatic injuries eligible for treatment in the WTC Medical Monitoring and Treatment Program that preceded the WTC Health Program; moreover, the PHS Act uses this date as the treatment cut-off date to identify musculoskeletal disorders eligible for certification in responders.

Finally, the reviewer found that the examples of acute traumatic injuries identified in the NPRM Summary of Proposed Rule were unnecessary and confusing, appearing to attribute "causality to non-causal events." With regard to the examples of acute traumatic injury offered in the Summary of Proposed Rule, the Administrator agrees; the sentence could be construed as not differentiating between causes and outcomes. This language was used in the Summary of Proposed Rule section of the NPRM preamble not to attribute causation, but to illustrate the types of injuries that the Program would find "acute" and "traumatic." This language is removed from the final rule and the Administrator will provide Program guidance to CCE and NPN physicians on the identification of acute traumatic injuries that could be considered WTC-related.

B. Public Comment

Support for acute traumatic injuries

Nearly all commenters expressed support for the addition of acute traumatic injury to the List. Although some submissions only addressed the addition of new-onset COPD, no commenters opposed the addition of acute traumatic injury.

Acute traumatic injury medical care cut-off date

One commenter offered support for the September 11, 2003 cut-off date. Three commenters expressed concern about the proposal to require responders or survivors who seek certification for an acute traumatic injury to have received medical care prior to September 11, 2003. Commenters suggested that the time period should be replaced with a simple requirement that the injury had to have been documented in medical records, even if the member did not receive treatment for the acute traumatic injury. Alternatively, commenters suggested that the September 11, 2003 date should be pushed back to 2004 to accommodate those responders or survivors who may not have recognized the extent of their injuries and, therefore, did not seek treatment prior to September 11, 2003, or those who either lost their medical records or can no longer obtain them from emergency rooms or private physicians.

Requiring only that the acute traumatic injury appear in the WTC Health Program member's medical record, regardless of treatment, would not accomplish the Administrator's intent to ensure, to the extent possible, that the member's acute traumatic injury was sustained during or in the aftermath of the September 11, 2001, terrorist attacks. By requiring that members demonstrate

that they received timely treatment for acute traumatic injuries, the Administrator will better be able to establish a medical history linking the member's current chronic injury or medically associated health condition to an acute traumatic injury that resulted from that individual's 9/11 exposure. As discussed above, the Administrator has determined that the September 11, 2003 cut-off date for medical treatment is supported, and has not identified any evidence to support extending the cut-off date for another year.

Medically associated health conditions

Two submissions addressed the matter of health conditions medically associated with WTC-related acute traumatic injury. One commenter offered a first-hand account of the health conditions he incurred as a result of the September 11, 2001, terrorist attacks, suggesting that he still suffers from medically associated conditions. The other commenter expressed concern that health conditions medically associated with WTC-related health conditions were not specifically addressed in the NPRM, particularly with regard to acute traumatic injury.

Health conditions medically associated with WTC-related health conditions were briefly addressed in the

NPRM.³³ The Administrator expects that many Program members who experienced an acute traumatic injury may no longer be dealing with the primary injury, but are in need of ongoing medical care for chronic conditions stemming from the original injury. For example, a WTC responder may have suffered a head trauma during response activities which was resolved years ago, but may still be coping with the long-term effects of TBI. Once WTC-related acute traumatic injury is added to the List, the WTC responder's TBI may be eligible for certification as a condition medically associated with the WTC-related acute traumatic injury, head trauma. Health conditions medically associated with a WTC-related health condition are determined by the Program on a case-by-case basis, in accordance with published Program regulations and policies and procedures.

VII. How to Get Help for WTC-Related Health Conditions

One commenter described suffering from untreated, chronic health issues that may stem from work at Ground Zero. Although this comment was not directly related to the rulemaking, the Administrator wants to remind individuals who may have responded to or survived the September 11,

³³ See 80 FR 54746 at 54756.

2001, terrorist attacks, that the WTC Health Program provides medical monitoring and treatment for WTC-related health conditions. An individual may apply to become a WTC Health Program member by filling out the appropriate application, available on the Program's website here: <http://www.cdc.gov/wtc/apply.html> (call 1-888-982-4748 to discuss the application process).

VIII. Summary of Final Rule

For the reasons discussed above and in the NPRM, the Administrator amends 42 CFR 88.1, "List of WTC-related health conditions," paragraph (1)(v), to add "new-onset" COPD to the existing "WTC-exacerbated chronic obstructive pulmonary disease (COPD)." This will permit the WTC Health Program to certify cases of COPD determined to have been caused or contributed to by 9/11 exposures (considered "new-onset" cases), in addition to those cases of COPD which were exacerbated by 9/11 exposures and which are already included on the List.

For the reasons discussed above, the Administrator also adds "WTC-related acute traumatic injury" to the List for WTC responders and screening- and certified-eligible survivors who received medical treatment for such an injury

on or before September 11, 2003. The term "WTC-related acute traumatic injury" is defined as a type of injury characterized by physical damage to a person's body that must have been caused by and occurred immediately after exposure to hazards or adverse conditions characterized by a one-time exposure to energy resulting from the terrorist attacks or their aftermath. This requirement is intended to distinguish these types of injuries from musculoskeletal disorders, which are already included on the List of WTC-Related Health Conditions. As required by statute, WTC-related musculoskeletal disorders are considered to be caused by repetitive motion or heavy lifting; the health condition "WTC-related acute traumatic injury" requires a demonstration of causation by a specific event or incident. Symptoms of acute traumatic injuries may not immediately manifest after the specific event or incident. The Administrator will issue guidance to CCE and NPN physicians on the identification of WTC-related acute traumatic injury. WTC-related acute traumatic injury includes, but is not limited to the following: eye injury; burn; head trauma; fracture; tendon tear; complex sprain; and other similar injuries. The term "WTC-related" was not included in the term proposed in the NPRM; however, the Administrator finds that adding it would result in no

substantive change from the proposed rule. It would be in keeping with the existing definition of "WTC-related musculoskeletal disorder" and would also signal that this language was developed specifically for the purposes of the WTC Health Program. Finally, to clarify the Administrator's intent, the regulatory text is reorganized slightly from that which was proposed. The reorganization has no substantive effect.

IX. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This rulemaking has been determined not to be a "significant regulatory action" under section 3(f) of

Executive Order 12866. This rule adds new-onset COPD³⁴ and WTC-related acute traumatic injury to the List of WTC-Related Health Conditions established in 42 CFR 88.1. This rulemaking is estimated to cost the WTC Health Program from \$4,602,162 to \$5,666,713 annually, between 2016 and 2019.³⁵ All of the costs to the WTC Health Program will be transfers due to the implementation of provisions of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111-148) on January 1, 2014. This rulemaking has not been reviewed by the Office of Management and Budget (OMB). The rule would not interfere with State, local, and Tribal governments in the exercise of their governmental functions.

Population estimates

As of December 1, 2015, the WTC Health Program had enrolled 64,384 responders and 9,358 survivors (73,742 total). Of that total population, 56,207 responders and 4,772 survivors (60,979 total) were participants in

³⁴ WTC-exacerbated COPD is a statutorily covered condition pursuant to PHS Act, sec. 3312(a)(3)(A)(v); this NPRM proposes to add new-onset COPD occurring after 9/11 exposures.

³⁵ The low cost estimate reflects the 2016 undiscounted new-onset COPD treatment cost estimate using WTC Health Program data from Table 5 and the 2016 undiscounted WTC-related acute traumatic injury treatment cost estimate from Table 6. The high cost estimate reflects the high new-onset COPD treatment cost estimate for 2019, discounted at 3 percent, using data from Leigh *et al.* from Table 5 and the WTC-related acute traumatic injury treatment cost estimate for 2019, discounted at 3 percent, from Table 6. Future cost and prevalence estimates are discounted at 3% and 7% in accordance with OMB Circular A-94, Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs. The estimates are discounted in order to compute net present value.

previous WTC medical programs and were 'grandfathered' into the WTC Health Program established by Title XXXIII of the PHS Act.³⁶ From July 1, 2011 to December 1, 2015, 8,177 new responders and 4,586 new survivors (12,763 total) enrolled in the WTC Health Program. For the purpose of calculating a baseline estimate of new-onset COPD and WTC-related acute traumatic injury prevalence, the Administrator projected that new enrollment would be approximately 4,000 per year (2,800 new responders and 1,200 new survivors), based on the trend in enrollees through December 1, 2015.

CCE or NPN physicians will conduct medical assessments for patients as appropriate and make a determination, which the Administrator will then use to certify or not certify the health condition (in this case, new-onset COPD or a type of WTC-related acute traumatic injury) for treatment by the WTC Health Program. However, for the purpose of this analysis, the Administrator has assumed that all diagnosed cases of new-onset COPD and acute traumatic injury will be certified for treatment by the WTC Health Program. Finally, because there are no existing data on new-onset COPD rates related to 9/11 exposures at either the Pentagon or Shanksville, Pennsylvania sites, and only limited data on

³⁶ These grandfathered members were enrolled without having to complete a new member application when the WTC Health Program started on July 1, 2011 and are referred to in the WTC Health Program regulations in 42 CFR part 88 as "currently identified responders" and "currently identified survivors."

acute traumatic injuries at the Pentagon, the Administrator has used only data from studies of individuals who were responders or survivors in the New York City area.

Prevalence of new-onset COPD

To estimate the number of potential cases of WTC-related new-onset COPD to be certified for treatment by the WTC Health Program, we first subtracted the number of current members certified for an obstructive airways disease (OAD), including WTC-exacerbated COPD, from the total number of members.³⁷ We then reviewed the surveillance literature to determine a prevalence rate for new-onset COPD among the non-OAD certified members. In studies of FDNY members with known pre-9/11 health status and high WTC exposure, Aldrich et al. reported that 2 percent of FDNY firefighters had an FEV1% below 70 percent of predicted³⁸ at year 1 after September 11, 2001 (a proportion that doubled

³⁷ Cases of COPD diagnosed prior to September 11, 2001, are presumed to be eligible for coverage as WTC-exacerbated COPD and therefore would not need coverage under new-onset COPD. Members already certified for an obstructive airway disease are also removed from the analysis because any progression to COPD (*i.e.*, airflow limitation not fully reversible with bronchodilator) from their current certified WTC-related OAD condition could be considered a health condition medically-associated with the certified WTC-related OAD condition. See John Howard, Administrator of the WTC Health Program, Health Conditions Medically Associated with World Trade Center-Related Health Conditions, revised Nov. 7, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHealthMedically%20AssociatedHealthConditions7November2014.pdf>.

³⁸ The term of art "percent of predicted" means that the proportion of the patient's vital capacity expired in 1 second of forced expiration (FEV1%) is less than the predicted average FEV1% in the population for a person of similar age, sex, and body composition. FEV1% predicted is a marker for severity of airway obstruction. In the setting of post-bronchodilator FEV1/FVC ≤ 0.7 , FEV1% predicted ≥ 80 indicates mild COPD; 50-80, moderate; 30-50, severe, and < 30 , very severe. See American Thoracic Society COPD Guidelines, Spirometric Classification, 2015, <http://www.thoracic.org/copd-guidelines/for-health-professionals/definition-diagnosis-and-staging/spirometric-classification.php>.

6.5 years later), and Webber et al.³⁹ reported an approximate 4 percent prevalence of new-onset, self-reported, physician-diagnosed COPD/emphysema nearly ten years after rescue/recovery efforts at the WTC site. Because pre-9/11 health records were not available in studies of WTC survivors, the Administrator has determined that the 4 percent prevalence of new-onset COPD will be applied to survivor estimates as well.⁴⁰ We applied the 4 percent prevalence to the number of remaining members and also to the projected annual enrollment of 4,000 new members to estimate the number of potential WTC-related new-onset COPD cases in 2016. (See Table 1, below)

Table 1. Estimated prevalence of 2016-2019 new-onset COPD cases				
	2016	2017	2018	2019
Responders	2,106	2,218	2,330	2,442
Survivors	306	354	402	450
Total	2,412	2,572	2,732	2,892

Prevalence of WTC-related acute traumatic injury

While this rulemaking would make acute traumatic injury eligible for certification, the Administrator assumes that the conditions most likely to receive

³⁹ Mayris Webber, Michelle Glaser, Jessica Weakley, et al., Physician-Diagnosed Respiratory Conditions and Mental Health Symptoms 7-9 Years Following the World Trade Center Disaster, *AJIM* 2011;54:661-671.

⁴⁰ The 4 percent prevalence of new-onset COPD that was observed among firefighters was used to estimate the number of expected cases of new-onset COPD in the entire exposed cohort and may result in an overestimation because of the differences in initial exposure intensity between responders and survivors.

treatment within the WTC Health Program will be those medically associated conditions which are the long-term consequences of the certified WTC-related acute traumatic injury. Health conditions medically associated with WTC-related health conditions are determined on a case-by-case basis in accordance with WTC Health Program regulations and policies and procedures.⁴¹ Examples of such health conditions medically associated with a WTC-related acute traumatic injury may include chronic back pain caused by vertebrae fractures, chronic peripheral neuropathy due to severe burns, and problems with executive brain function due to closed head injuries.

Although we were able to estimate from the surveillance literature the number of responders and survivors who received medical treatment for acute traumatic injuries on or in the aftermath of September 11, 2001, we do not know the number of individuals who still experience health problems because of those traumatic injuries and are in need of chronic care. To project this, we estimated the number of persons in the responder and survivor populations with WTC-related acute traumatic injury by deriving estimates from the Berrios-Torres et

⁴¹ John Howard, Administrator of the WTC Health Program, Health Conditions Medically Associated with World Trade Center-Related Health Conditions, revised Nov. 7, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHEMeditally%20AssociatedHealthConditions7November2014.pdf>.

al.,⁴² Banauch et al.,⁴³ Perritt et al.,⁴⁴ and NYCDOH studies.⁴⁵ Using the estimated prevalence for injury types, we then calculated the prevalence for these injuries among the responder⁴⁶ and survivor⁴⁷ populations. We applied that prevalence to the number of current and expected WTC Health Program members to find the number of individuals who may have suffered a WTC-related acute traumatic injury. Next, in order to estimate the proportion of those in the responder and survivor populations who suffered WTC-related acute traumatic injuries that require chronic care, we assumed that all patients with permanent partial and permanent total impairment caused by acute traumatic injuries will require chronic medical care and will enroll in the WTC Health Program. The National Safety Council

⁴² Sandra Berrios-Torres, Jane Greenko, Michael Philips, et al., World Trade Center Rescue Worker Injury and Illness Surveillance, New York, 2001, Am J Prev Med 2003;25(2):79-87.

⁴³ G Banauch, M McLaughlin, R Hirschhorn, et al., Injuries and Illnesses among New York City Fire Department Rescue Workers after Responding to the World Trade Center Attacks, MMWR Sept. 11, 2002;51(Special Issue):1-5.

⁴⁴ Kara Perritt, Winifred Boal, The Helix Group Inc., Injuries and Illnesses Treated at the World Trade Center, 14 September -- 20 November 2001, Prehosp Disaster Med 2005;20(3).

⁴⁵ New York City Department of Health, Rapid Assessment of Injuries Among Survivors of the Terrorist Attack on the World Trade Center -- New York City, September 2001, MMWR Jan. 11, 2002;51(01):1-5.

⁴⁶ The responder estimate is subject to two main assumptions. First, Banauch et al. reported on FDNY members from September 11 to December 10, 2001, and we assume no additional injuries from December 11, 2001 until the site was closed in July 2002. The time period reported on by Banauch et al. likely encompasses a large majority of the injuries suffered by FDNY members. Second, Perritt et al. did not report directly on closed head injuries; therefore the number of closed head injuries reported by Berrios-Torres et al. for responders is used.

⁴⁷ We estimate the survivor prevalence from the NYCDOH study reports on survivors during the period from September 11-13, 2001. Although we understand that this reporting period likely encompasses a majority of the survivors who were injured, because the number of cases is based on those survivors who were treated for injuries only within the first 48 hours after the terrorist attacks, the reported number of cases likely underestimates the total number of survivors who sustained acute traumatic injuries as a result of the September 11, 2001, terrorist attacks.

estimated that 3.8 percent of non-fatal disabling injuries⁴⁸ are associated with permanent partial or permanent total impairment.⁴⁹ We applied that estimate to the estimated number of current and expected WTC Health Program members who may have suffered a WTC-related acute traumatic injury to determine the number of individuals with WTC-related acute traumatic injury who are in need of chronic care. (See Table 2, below.)

Table 2. Estimated prevalence of 2016-2019 WTC-related acute traumatic injury cases				
	2016	2017	2018	2019
Responders	80	83	86	89
Survivors	10	12	13	14
Total	90	95	99	103

Costs of COPD treatment

The Administrator estimated the medical treatment costs associated with new-onset COPD in this rulemaking, using the methods described below, to be between \$1,665 and \$1,930 per case in 2014.

The low estimate, \$1,665 per case, was based on WTC Health Program costs associated with the treatment of WTC-exacerbated COPD for the period October 1, 2013 through September 30, 2014. These medical costs include both

⁴⁸ In 2011, the National Safety Council replaced the term "disabling injury" with "medically consulted injury." See National Safety Council, Injury Facts, 2014.

⁴⁹ A non-fatal disabling injury is one which results in some degree of permanent impairment or renders the injured person unable to effectively perform his regular duties or activities for a full day beyond the day of the injury. National Safety Council, Injury Facts, 1986.

medical services and pharmaceuticals.⁵⁰

The high estimate, \$1,930 per case, was based on a study by Leigh et al.⁵¹ The authors estimated the cost of occupational COPD by aggregating and analyzing national data sets collected by the National Center for Health Statistics, the Health Care Financing Administration, and other government agencies and private firms. They concluded that there were an estimated 2,395,650 occupational cases of COPD in 1996 that resulted in medical costs estimated at \$2.425 billion. Medical costs included payments to hospitals, physicians, nursing homes, and vendors of medical supplies, including oxygen, and also included the cost of pharmaceuticals.⁵² The medical cost per case was about \$1,012 in 1996 dollars or about \$1,930 in 2014 dollars, after adjusting for inflation using the Medical Consumer Price Index for all urban consumers.⁵³

Table 3 below shows medical treatment cost estimates per COPD case in 2016-2019:

Source	Year	Undiscounted	Discounted 3%	Discounted 7%
WTC Health	2016	\$1,665	--	--

⁵⁰ Pharmaceutical costs are estimated to be approximately 38 percent of total treatment costs.

⁵¹ J. Paul Leigh, Patrick Romano, Marc Schenker, Kathleen Kreiss, Costs of Occupational COPD and Asthma, CHEST 2002;121(1):264-272.

⁵² Screening costs are not included because the U.S. Preventive Services Task Force does not recommend screening for COPD. See Screening for Chronic Obstructive Pulmonary Disease Using Spirometry, <http://www.uspreventiveservicestaskforce.org/uspstf/uspscopd.htm>.

⁵³ Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers: Medical Care, <https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419>.

Program	2017	1,665	\$1,617	\$1,556
	2018	1,665	1,569	1,454
	2019	1,665	1,524	1,359
Leigh et al.	2016	1,930	--	--
	2017	1,930	1,874	1,804
	2018	1,930	1,819	1,686
	2019	1,930	1,766	1,575

Costs of WTC-related acute traumatic injury treatment

The Administrator estimated the medical treatment costs associated with WTC-related acute traumatic injury in this rulemaking using the methods described below. Because it is not possible to identify all possible types of acute traumatic injury for which a WTC responder or survivor might seek certification, we have identified several types of acute traumatic injury that may be representative of those types of acute traumatic injuries that might be certified by the WTC Health Program. Representative examples of types of WTC-related acute traumatic injury include closed head injuries, burns, fractures, strains and sprains, orthopedic injuries (e.g., meniscus tear), ocular injuries, and crush injuries. The WTC Health Program estimates the cost of providing medical treatment for WTC-related acute traumatic injury to be around \$11,216 per case in 2014 dollars.

This cost figure was based on a study by the National

Council on Compensation Insurance (NCCI).⁵⁴ The data source used in this study was NCCI’s Medical Data Call (MDC). The MDC captures transaction-level detail on workers’ compensation medical bills processed on or after July 1, 2010, including dates of service, charges, payments, procedure codes, and diagnosis codes; pharmaceutical costs are also included. The data used in this study were evaluated as of March 2013 for:

- Long-term medical services provided in 2011 and 2012 (i.e., 20 to 30 years post injury)
- Injuries occurring between 1983 and 1990
- Claimants with dates of birth between 1920 and 1970
- States for which NCCI collects MDC⁵⁵

For individuals born during 1951-1970, the medical cost per case was about \$11,216 in 2014 dollars, after adjusting for inflation using the Medical Consumer Price Index for all urban consumers.⁵⁶

Table 4 below shows medical treatment cost estimates per acute traumatic injury case in 2016-2019:

Table 4. Estimated medical treatment costs per WTC-related acute traumatic injury case during 2016-2019 in 2014 dollars				
Source	Year	Undiscounted	Discounted	Discounted

⁵⁴ David Colón, The Impact of Claimant Age on Late-Term Medical Costs, NCCI Research brief, Oct. 2014, <https://www.ncci.com/documents/Impact-Claimant-Age-Late-Term-Med-Costs.pdf>.

⁵⁵ AK, AL, AR, AZ, CO, CT, DC, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MN, MO, MS, MT, NC, NE, NH, NJ, NM, NV, NY, OK, OR, RI, SC, SD, TN, UT, VA, VT, WI, and WV.

⁵⁶ Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers: Medical Care, <https://research.stlouisfed.org/fred2/series/CPIMEDSL/downloaddata?cid=32419>.

			3%	7%
NCCI	2016	\$11,216	--	--
	2017	11,216	\$10,890	\$10,482
	2018	11,216	10,572	9,796
	2019	11,216	10,264	9,156

Summary of Costs

This rulemaking is estimated to cost the WTC Health Program from \$4,602,162 to \$5,666,713 annually, between 2016 and 2019.⁵⁷ The analysis above offers an assumption about the number of individuals who might enroll in the WTC Health Program and estimates the number of new-onset COPD and WTC-related acute traumatic injury cases and the resulting estimated treatment costs to the WTC Health Program. For the purpose of computing the treatment costs for new-onset COPD and WTC-related acute traumatic injury, the Administrator assumed that all of the individuals who are diagnosed with either condition will be certified by the WTC Health Program for treatment services. In the calculations found in Tables 5 and 6, below, estimated treatment costs were applied to the estimated number of cases of new-onset COPD and WTC-related acute traumatic injury. We assumed that 9 percent of new-onset COPD costs and 12 percent of WTC-related acute traumatic injury costs

⁵⁷ The low cost estimate reflects the 2016 undiscounted new-onset COPD treatment cost estimate using WTC Health Program data from Table 5 and the 2016 undiscounted WTC-related acute traumatic injury treatment cost estimate from Table 6. The high cost estimate reflects the high new-onset COPD treatment cost estimate for 2019, discounted at 3 percent, using data from Leigh *et al.* from Table 5 and the WTC-related acute traumatic injury treatment cost estimate for 2019, discounted at 3 percent, from Table 6. NB: The cost estimate provided in the NPRM included only the years 2015 and 2016, and costs were provided in the aggregate.

for responders may be covered by workers' compensation each year; accordingly, we adjusted only the responder estimates to clarify that 91 percent of COPD costs and 88 percent of WTC-related acute traumatic injury costs will be paid by the WTC Health Program.⁵⁸ This analysis does not include administrative costs associated with certifying additional diagnoses of new-onset COPD or WTC-related acute traumatic injury that are WTC-related health conditions that might result from this action. Those costs were addressed in the interim final rule that established regulations for the WTC Health Program.⁵⁹

Since the implementation of provisions of the ACA on January 1, 2014, all of the members and future members are assumed to have or have access to medical insurance coverage other than through the WTC Health Program. Therefore, all treatment costs to be paid by the WTC Health Program through 2019 are considered transfers. Tables 5 and 6 describe the estimated allocation of WTC Health Program transfer payments.

Table 5. Medical treatment cost for new-onset COPD cases during 2016-2019 in 2014 dollars				
Source (costs)	Year	Undiscounted	Discounted 3%	Discounted 7%
WTC		Responders		

⁵⁸ Workers' compensation rates are derived from WTC Health Program data. See WTC Health Program, Policy and Procedures for Recoupment and Coordination of Benefits: Workers' Compensation Payment, revised Dec. 16, 2013, <http://www.cdc.gov/wtc/pdfs/WTCHP-PP-Recoupment-WComp-16-Dec-13.pdf>.

⁵⁹ 76 FR 38914 (July 1, 2011).

Health Program	2016		--	--	
	2017	\$1,665*2,106*.91 =\$3,190,906	\$1,617*2,218*.9 1	\$1,556*2,218*.9 1	
	2018	\$1,665*2,218*.91 =\$3,360,603	= \$3,263,720 \$1,569*2,330*.9 1	= \$3,140,599 \$1,454*2,330*.9 1	
	2019	\$1,665*2,330*.91 =\$3,530,300	= \$3,326,751 \$1,524*2,442*.9 1	= \$3,082,916 \$1,359*2,442*.9 1	
		\$1,665*2,442*.91 =\$3,699,996	= \$3,386,663	= \$3,019,997	
	Survivors				
	2016	\$1,665*306 =\$509,490	--	--	
	2017	\$1,665*354 =\$589,410	\$1,874*354 =\$663,396	\$1,804*354 =\$638,616	
	2018	\$1,665*402 =\$669,330	\$1,819*402 =\$731,238	\$1,686*402 =\$677,772	
	2019	\$1,665*450 =\$749,250	\$1,766*450 =\$794,700	\$1,575*450 =\$708,750	
	Total (low estimates)				
	2016	\$3,700,396	--	--	
	2017	\$3,950,013	\$3,927,116	\$3,779,215	
	2018	\$4,199,630	\$4,057,989	\$3,760,688	
	2019	\$4,449,246	\$4,181,363	\$3,728,747	
Leigh et al.	Responders				
	2016		--	--	
	2017	\$1,930*2,106*.91 =\$3,698,768	\$1,874*2,218*.9 1	\$1,804*2,218*.9 1	
	2018	\$1,930*2,218*.91 =\$3,895,473	= \$3,782,444 \$1,819*2,330*.9 1	= \$3,641,158 \$1,686*2,330*.9 1	
	2019	\$1,930*2,330*.91 =\$4,092,179	= \$3,856,826 \$1,766*2,442*.9 1	= \$3,574,826 \$1,575*2,442*.9 1	
		\$1,930*2,442*.91 =\$4,288,885	= \$3,924,441	= \$3,499,997	
	Survivors				
	2016	\$1,930*306 =\$590,580	--	--	
	2017	\$1,930*354 =\$683,220	\$1,874*354 =\$663,396	\$1,804*354 =\$638,616	
	2018	\$1,930*402 =\$775,860	\$1,819*402 =\$731,238	\$1,686*402 =\$677,772	
	2019	\$1,930*450 =\$868,500	\$1,766*450 =\$794,700	\$1,575*450 =\$708,750	
	Total (high estimates)				
	2016	\$4,289,348	--	--	
	2017	\$4,578,693	\$4,445,840	\$4,279,774	
	2018	\$4,868,039	\$4,588,064	\$4,252,598	
2019	\$5,157,385	\$4,719,141	\$4,208,747		

Table 6. Medical treatment cost for WTC-related acute traumatic injury cases during 2016-2019 in 2014 dollars

Source (costs)	Year	Undiscounted	Discounted 3%	Discounted 7%
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		Responders		
NCCI	2016	\$11,216*80*.88 =\$789,606	--	--
	2017	\$11,216*83*.88 =\$819,217	\$10,890*83*.88 =\$795,406	\$10,482*83*.88 =\$765,605
	2018	\$11,216*86*.88 =\$848,827	\$10,572*86*.88 =\$800,089	\$9,796*86*.88 =\$741,361
	2019	\$11,216*89*.88 =\$878,437	\$10,264*89*.88 =\$803,876	\$9,156*89*.88 =\$717,098
	Survivors			
	2016	\$11,216*10 =\$112,160	--	--
	2017	\$11,216*12 =\$134,592	\$10,890*12 =\$130,680	\$10,482*12 =\$125,784
	2018	\$11,216*13 =\$145,808	\$10,572*13 =\$137,436	\$9,796*13 =\$127,348
	2019	\$11,216*14 =\$157,024	\$10,264*14 =\$143,696	\$9,156*14 =\$128,184
	Total			
	2016	\$901,766	--	--
	2017	\$953,809	\$926,086	\$891,389
	2018	\$994,635	\$937,525	\$868,709
	2019	\$1,035,461	\$947,572	\$845,282

Examination of benefits (health impact)

This section describes qualitatively the potential benefits of the rule in terms of the expected improvements in the health and health-related quality of life of potential new-onset COPD or WTC-related acute traumatic injury patients treated through the WTC Health Program, compared to no treatment by the Program.

The Administrator does not have information on the health of the population that may have experienced 9/11 exposures and is not currently enrolled in the WTC Health Program. However, the Administrator assumes that all unenrolled responders and survivors are now covered by health insurance (due to the ACA) and may be receiving

treatment outside the WTC Health Program.

Although the Administrator cannot quantify the benefits associated with the WTC Health Program, members with new-onset COPD or WTC-related acute traumatic injury would have improved access to care and, thereby, the Program should produce better treatment outcomes than in its absence. Under other insurance plans, patients may have deductibles, coinsurance, and copays, which impact access to care and timeliness of care. WTC Health Program members who are certified for these conditions would have first-dollar coverage and, therefore, are likely to seek care sooner when indicated, resulting in improved treatment outcomes.

Limitations

The analysis presented above was limited by the dearth of verifiable data on the new-onset COPD and acute traumatic injury status of responders and survivors who have yet to apply for enrollment in the WTC Health Program. Because of the limited data, the Administrator was not able to estimate benefits in terms of averted healthcare costs. Nor was the Administrator able to estimate indirect costs such as averted absenteeism, short and long-term disability, and productivity losses averted due to

premature mortality.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The Administrator believes that this rule has "no significant economic impact upon a substantial number of small entities" within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. This rule does not contain any information collection requirements; thus, HHS has determined that the PRA does not apply to this rule.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801

et seq., HHS will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 et seq., directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million in 1995 dollars by State, local, or Tribal governments in the aggregate, or by the private sector. However, the rule may result in an increase in the contribution made by New York City for treatment and monitoring, as required under the PHS Act, section 3331(d)(2).

F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. This rule

has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Administrator has reviewed this rule in accordance with Executive Order 13132 regarding Federalism, and has determined that it does not have "Federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, the Administrator has evaluated the environmental health and safety effects of this rule on children. The Administrator has determined that the rule would have no environmental health and safety effect on children.

I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, the Administrator has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal government administers or enforces. The Administrator has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 88

Administrative practice and procedure, Health care, Lung diseases, Mental health programs.

Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 88 as follows:

PART 88--WORLD TRADE CENTER HEALTH PROGRAM

1. The authority citation for part 88 is revised to read as follows:

Authority: 42 U.S.C. 300mm to 300mm-61, Pub. L. 111-347, 124 Stat. 3623, as amended by Pub. L. 114-113, 129 Stat. 2242.

2. In § 88.1, under the definition "List of WTC-related health conditions," revise paragraph (1)(v) and add paragraph (5) to read as follows:

§ 88.1 Definitions.

* * * * *

List of WTC-related health conditions

* * * * *

(1) * * *

(v) WTC-exacerbated and new-onset chronic obstructive pulmonary disease (COPD).

* * * * *

(5) Acute traumatic injuries:

(i) WTC-related acute traumatic injury: physical damage to the body caused by and occurring immediately after a one-time exposure to energy, such as heat, electricity, or impact from a crash or fall, resulting from a specific event or incident. For a WTC responder or screening-eligible or certified-eligible survivors who received any medical treatment for a WTC-related acute traumatic injury on or before September 11, 2003, such health condition includes:

- (A) Eye injury.
 - (B) Burn.
 - (C) Head trauma.
 - (D) Fracture.
 - (E) Tendon tear.
 - (F) Complex sprain.
 - (G) Other similar acute traumatic injuries.
- (ii) [Reserved]

Dated: June 27, 2016.

John Howard,
Administrator, World Trade Center Health Program and
Director, National Institute for Occupational Safety and
Health, Centers for Disease Control and Prevention,
Department of Health and Human Services.

Sylvia M. Burwell,
Secretary, Department of Health and Human Services.

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